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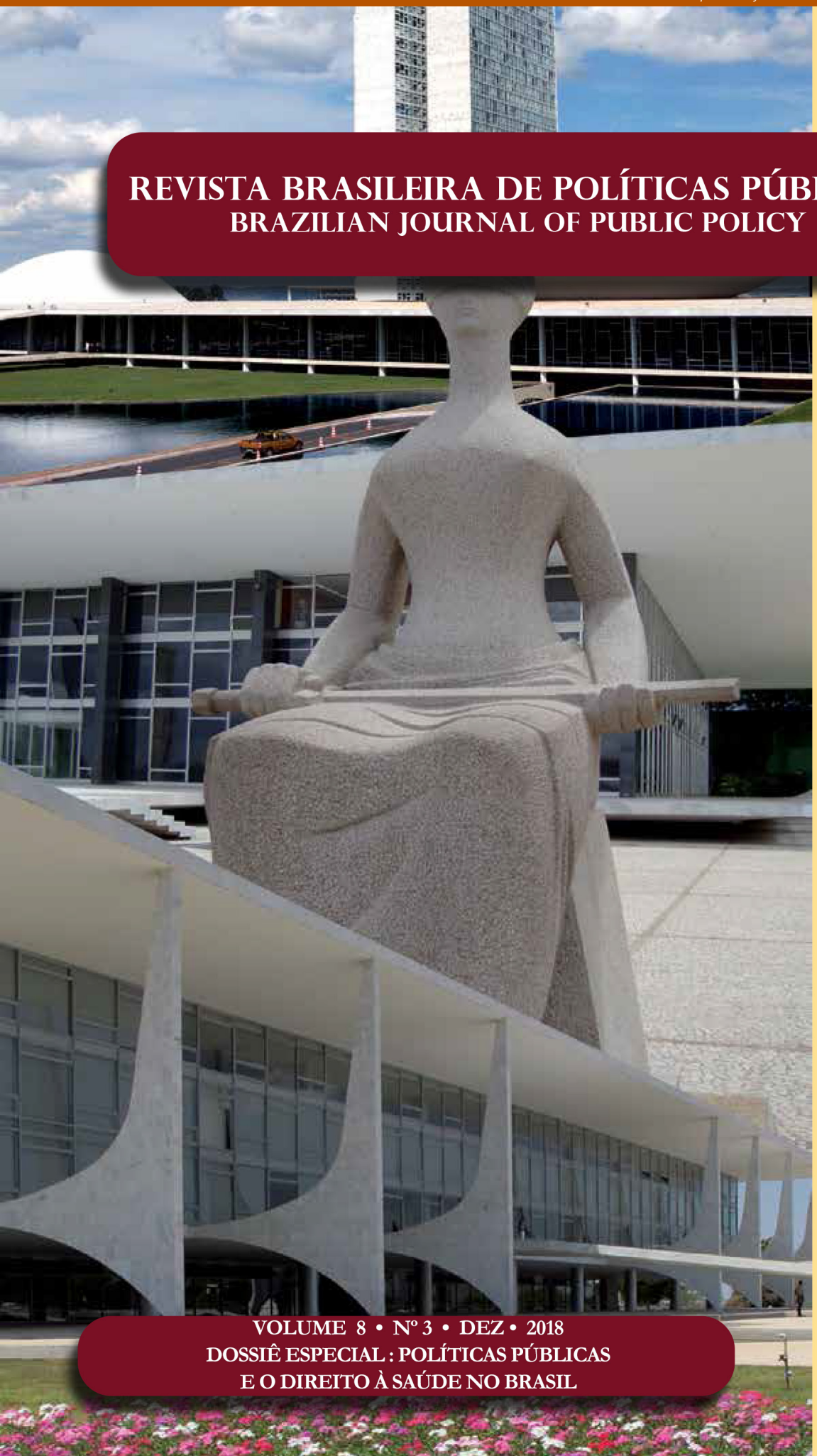
ISSN 2236-1677

REVISTA BRASILEIRA DE POLÍTICAS PÚBLICAS
BRAZILIAN JOURNAL OF PUBLIC POLICY



Prohibition to add aroma and flavor to smoking products: what is the limit of the regulatory power of the Brazilian Health Regulatory Agency?

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Joedson de Souza Delgado

Ivo Teixeira Gico Júnior

VOLUME 8 • Nº 3 • DEZ • 2018

DOSSIÊ ESPECIAL : POLÍTICAS PÚBLICAS
E O DIREITO À SAÚDE NO BRASIL

Sumário

doi: 10.5102/rbpp.v8i3.5249

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Proibição de acrescentar aroma e sabor nos produtos fumígenos: qual o limite do poder normativo da Agência Nacional de Vigilância Sanitária?

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Abstract

In this study, we investigate whether the regulatory power of the Brazilian Health Regulatory Agency (Anvisa) has violated the law and the Federal Constitution. We demonstrate this with the (in)decision of the Plenary of the Federal Supreme Court concerning the (in)validity of the sanitary regulation which has prohibited the tobacco industry in the country from adding essences of flavor and aroma to tobacco smoke products. As a problem, we see the limited regulatory function of Anvisa, which, by taking into account the conflicting interests of the market, includes the identification of problems with regulatory elements involving technical and legal requirements as well as political regulation. We will use the deductive method with a qualitative approach of the case study referent to the (un)constitutionality of the Resolution of the Board of Directors, RDC No. 14, of March 15, 2012, oriented towards the discussion about Anvisa's regulatory capacity versus the limits of its competency established by primary standards issued by the National Congress. We conclude that Anvisa has issued Resolution RDC No. 14, of 2012, which contains sufficient legal characteristics to authorize its impugnation before the Constitution.

Keywords: Brazilian Health Regulatory Agency. Jurisprudence. Government Regulation. Smoke-Free Policy. Tobacco Products. Flavoring Agents.

Resumo

Neste estudo, investigamos se o poder normativo da Agência Nacional de Vigilância Sanitária (Anvisa) tem violado a lei e a Constituição Federal, a qual ilustramos com a (in)decisão do Plenário do Supremo Tribunal Federal sobre a (in)validade da norma sanitária que proibiu a indústria tabagista de adicionar essências de sabor e aroma aos produtos fumígenos derivados do tabaco comercializados no País. Como problema tem-se a limitação da função regulatória da Anvisa que inclui o diagnóstico dos elementos normativos

* Recebido em 09/05/2018
Aprovado em 08/06/2018

** Master in Law from the University Center of Brasília - UniCEUB; Specialist in Administrative Law from Institute of Public Law - IDP and specialist in Sanitary Law from the Osvaldo Cruz Foundation - Fiocruz / Brasília; Bachelor in Business Administration from the University of Brasília - UnB; Bachelor in Law from the University Center of the Federal District - UDF; Servant at the Brazilian Health Regulatory Agency – Anvisa. Email: joedson.delgado@hotmail.com .

*** PhD in Law at the Universidade de São Paulo – USP; PhD in Economics at the Universidade de Brasília – UnB; Master in Law (Summa Cum Laude) at the Columbia University in the City of New York; Bachelor of Laws at the Universidade de Brasília – UnB; Professor in the Postgraduate Program in Law at Centro Universitário de Brasília – UniCEUB; Attorney-at-Law. Email: gico@ghdadvogados.com.br .

– envolvendo a regulação técnico-jurídica e a regulação política –, ao levar em conta os interesses conflitantes do mercado. Utilizaremos o método dedutivo com abordagem qualitativa do estudo de caso referente à (in)constitucionalidade da Resolução da Diretoria Colegiada – RDC nº 14, de 15 de março de 2012 orientado à discussão sobre a capacidade normativa da Anvisa versus seu limite de competência estabelecido por normas primárias editadas pelo Congresso Nacional. Concluímos que a Anvisa editou a Resolução – RDC nº 14, de 2012 com característica de lei suficiente para autorizar sua impugnação perante a Constituição.

Palavras-chave: Agência Nacional de Vigilância Sanitária. Jurisprudência. Regulamentação Governamental. Política Antifumo. Produtos do tabaco. Aromatizantes.

1. Introduction

Based on the idea of an extensive public health system, health surveillance should be understood as the set of actions seeking to control health risks – by guaranteeing sanitary safety –, brought about by the consumption and/or production of goods and services.[1] In order to safeguard the access to health services, the Federal Government presented a new arrangement for the decentralized exercise of sanitary surveillance, based on Law No. 9,782, of January 26, 1999,[2] by creating Anvisa to replace the Bureau of Health Surveillance of the Ministry of Health, aiming to regulate the sector with a broad spectrum of competencies.

It is worth noting that the regulation goes beyond the simple issuance of regulatory acts on technical subjects falling within its scope, but also arises from the legislative function stemming from political power as defined by the majority during the electoral process.[3] The regulation exercised by Anvisa envisages decisions of a political nature as a result of a contemporary way of life directed towards consumption.

The idea of regulation, from a legal and political point of view, represents a delegation of powers by the Legislative, through the transfer of part of its main regulatory (or regulating) function to the agencies, as well as to the Executive itself, in order to stimulate the means of operating an indirect entity. From the point of view of public policies, it is an obligation of the President of the Republic, or his immediate assistants, to organize and set goals or objectives for governmental actions as provided in article 174 of the Federal Constitution.

It should be noted that the legislator opted for the transfer of the supervisory power to the regulatory agencies, so that they could issue secondary legal rules, in order to fulfill the particularities contained in the establishing law. To this end, the autarchies which were established under a special regime, together with regulating functions, perform executive, monitoring and sanctioning functions aimed at greater agility and administrative freedom. In practice, there are material and/or procedural setbacks that eventually refer the decisions of the agencies to the attention of the supervising minister, who acts as an appeal instance, for example, in matters concerning the issuing of licenses.[4]

Anvisa basks in some kind of functional autonomy in relation to the Ministry of Health, and for this reason, it has been recently involved in certain controversies related to regulatory actions on sensitive issues

1 VENCINA NETO, Gonzalo. Vigilância Sanitária. *Revista de Direito Sanitário,* São Paulo, v. 14, n. 3, p. 91, nov. 2013/fev. 2014. Available from: <http://dx.doi.org/10.11606/issn.2316-9044.v14i3p91-94>. Access on: 6 jan. 2018.

2 BRASIL. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. *Diário Oficial da União*, Brasília, 26 jan. 1999b. Available from: <http://www.planalto.gov.br/ccivil_03/leis/L9782.htm>. Access on: 20 Feb. 2018.

3 SOUTO, Marcos Juruena Villela. A Função Regulatória. In: SOUTO, Marcos Juruena Villela; MARSHALL, Carla C. (Coord.). *Direito Empresarial Público.* Rio de Janeiro: Lumen Juris, 2006.

4 BRASIL. Presidência da República. Casa Civil. *Análise e avaliação do papel das agências reguladoras no atual arranjo institucional brasileiro*: relatório do grupo de trabalho interministerial. Brasília: Congresso Nacional, 2003b. p. 15. Available from: <https://is.gd/oCpNBe>. Access on: 26 Feb. 2018.

and/or technologically complex matters, which, in part, has motivated this research. In its area of coverage, Anvisa has normative power to act in matters of sanitary regulation, which encompasses, in its array, activities of authorization, licensing and permits, as well as of taxes setting and standardization and provision of penalties.

In view of the above, we examine in this work the limits of Anvisa's normative power with emphasis in the Direct Unconstitutionality Action, ADI No. 4874, filed by the National Confederation of Industry, against the Resolution RDC No. 14, 2012, of Anvisa, which has prohibited scented and flavored smoke products. To do so, we analyzed how the regulatory competency stems from the preferences and behaviors of political players, who address the normative grid to the Executive Branch (laws, regulations and other rules issued by public authorities and by delegated entities) in order to regulate a given subject through a specific technical rule; we also analyzed whether Anvisa's regulatory practice has gone beyond the law of the regulated sector itself.

To do so, the methodological procedure used in this research was the deductive one, using a qualitative approach, with the case study and the content analysis, concerning the legal/political instruments related to the regulatory power of the agencies, in accord with the constitutional rules of competency in the standard setting.

Thus, in order to develop a deeper analysis of the issue, we structured this article into four parts. In terms of topics, we present the normative power of Anvisa, in general terms, and then deal with its regulatory practice in contrast with these of other regulatory agencies, especially with a probable self-limiting regulatory distinction. Next, we present how the external control by the Judicial Power works, together with the regulatory impetus of Anvisa, by imposing obligations considered basic to the tobacco industry, being an object of judicial questioning as to its legitimacy to intervene in the economic domain by prohibiting the use of additives, aromas and flavorings in smoke tobacco products.

We formulated our final considerations by presenting a new way of understanding the regulatory policy, in which we could determine that the subject is a permanent target of intense divergences. However, by analyzing it, it was possible to perceive, among other points, that the control mechanisms in the national regulatory environment clearly demonstrate the performance of the Three Powers in the regulatory context of Anvisa, usually in situations in which this Agency may have violated the limits of its regulatory competence.

2. Anvisa's Regulatory Practice

Anvisa's prerogative in this regard is based on the supremacy of the public interest or of the interest in health and, therefore, the private or public activities must be subordinated to the commands of sanitary standards. In this perspective, the understanding that sanitary standards are an administrative act of a specific nature, which has a legal structure similar to the law, remains.[5]

The individual is bound to the public interest, which seeks to ensure the protection of the human health against the imminent risks that a certain irregular productive activity may cause.In this scenario, the decisional process of the regulatory bodies uses the administrative procedure, the legal and institutional environment, and the neutrality of the administrative process, all of them based on the administrative procedural theory of the regulation.[6,7]

5 GOMES, Filipe Lobo; GONZAGA, Jorge Luiz; NÓBREGA, Marcos Antônio Rios da. A importância da análise comparada – porque entender a regulação norte-americana é importante para otimizar a regulação estatal brasileira. *Revista do Programa de Pós-Graduação em Direito da Universidade Federal da Bahia*, Salvador, BA, v. 27, n. 2, p. 99, a. 2017. Available from: <https://is.gd/cWj851>. Access on: 22 Feb. 2018.

6 ARANHA, Marcio Iorio. *Manual de Direito Regulatório:* fundamentos de Direito Regulatório. 4. ed. London: Laccademia Publishing, 2018. p. 37.

7 SALES, Claudino Carneiro. Tabagismo, modernidade e Direito Regulatório: Brasil e Estados Unidos em perspectiva. *Revista de*

Prohibiting the violation of the law has a distinctive repressive character, giving the opportunity to the contradictory and the full defense to verify noncompliance to the law, while precaution against risk has a general effect and a protective character. In order to avoid delays in correcting a procedure, the contradictory may be postponed in situations that put health at risk, considering the impossibility of predicting all the hypotheses mentioned by law and the unavailability of the right to life.

For this reason, Anvisa, based on its expert judgment, when aware of new facts that are harmful to health, can adopt preventive measures, regardless of regulation. An example of precaution is, as a principle, the standardization on Genetically Modifiable Organisms, given the uncertain danger of intentional consequences (characteristic of the introduced gene) and unintentional ones (whether they are predictable or not) that may arise from them.[8]

The prerogatives and powers of the Public Administration are guided by the public interest, to which the individual must submit and follow, such as the prerogative of self-enforceability that allows a public health officer to prohibit a commercial establishment from selling food unfit for consumption, regardless of a court order. For the sake of justice and common well-being, the state confers a series of powers and prerogatives that can combine its actions with those of the private sector to achieve these tasks.[9]

On the other hand, Anvisa must carry out its tasks strictly subjected to the protection of public health and in compliance with legal principles and fundamental rights, with the principles of reasonableness and proportionality, and with the contradictory, under penalty of illegality and termination of the act.

The performance of Anvisa's end activities, due to its regulatory function, presents some errors that the legislator intended to outlaw, such as informational imbalance, the awareness of the regulator, incomplete contracts, the creation of economic power, opportunistic behavior, and flawed monitoring.[10] In this sense, the jurisprudence considers that Anvisa's act of interference in the economic and social domain is valid, as long as it preserves the public interest, according to the following amendment:

> 1. The issuance by ANVISA of standard (RDC 217/2001), which requires the presentation of a pest control certificate by the ships indicated therein is not in violation of the principle of free initiative.
>
> 2. The Federal Constitution made it possible to limit the freedom of initiative through the intervention of the State when it assumes the role of legal agent and regulator of economic activity (main clause of article 174).
>
> 3. The sanitary surveillance rules that regulate the sanitary control of cargo and travelers transport operations are derived from the Administration´s police power, exercised in order to protect social interests. The public relevance of such activity legitimizes its monitoring and control, provided that the performance of the public entity is exercised without abuse or extrapolation of the regulatory power – as in this case.[11]

Direito Setorial e Regulatório, Brasília, v. 2, n. 2, p. 240, out. 2016. Available from: <https://is.gd/92hH1u>. Access on: 18 June 2018.

8 DELGADO, Joedson de Souza. Transgênicos: uma nova reconfiguração do trabalho e da natureza pela agricultura capitalista. *Boletim do Observatório Ambiental Alberto Ribeiro Lamego*, Campos dos Goytacazes, v. 9, n. 1, p. 146, jan./jun. 2015. Available from: <http://dx.doi.org/10.19180/2177-4560.v9n115-08>. Access on: 7 Jan. 2018.

9 GOLDFARB, Miguel Andrés. Servicíos publicos: caracterización, fundamentos y evolución en el derecho argentino. *Revista de Direito Econômico e Socioambiental,* Curitiba, v. 7, n. 2, p. 180, jul./dez. 2016. Available from: <http://dx.doi.org/10.7213/rev.dir.econ.socioambienta.07.002.AO09>. Access on: 13 Feb. 2018.

10 PINTO, Pedro Duarte. Melhores resultados regulatórios no diálogo entre as agências reguladoras e o Tribunal de Contas da União. *Revista do Mestrado em Direito da Universidade Católica de Brasília*, v. 8, n. 2, p. 207, jul./dez. 2014. Available from: <https://is.gd/pUb6Mw>. Access on: 7 dez. 2017.

11 In the original: "1. Não viola o princípio da livre iniciativa a edição, pelaANVISA, de norma (RDC 217/2001) que exige a apresentação, pelas embarcações nela indicadas, do certificado de desratização.

2. A Constituição Federal possibilitou a limitação da liberdade de iniciativa por meio da atuação interventiva do Estado quando este assume a função de agente normativo e regulador daatividadeeconômica(caput do art. 174).

3. As normas de vigilância sanitária que regulamentam o controle sanitário das operações de transporte de cargas e de viajantes decorrem do poder de polícia da Administração, exercido para a proteção dointeressesocial. A relevância pública de talatividadelegitima a sua fiscalização e o seu controle, desde que exercida a atuação do ente públicosem abuso nem extrapolação do poder regulamentar

In this case, it is realized that the regulatory power granted by the Union to Anvisa follows the rules of article 2, item III, of Law No. 9,782 of 1999,[12] which recommends the issuance of decrees and regulations for the strict compliance with the law. It is forbidden to dispose of such interests freely, given the supremacy of the public interest over the private one and the unavailability of public interests by the Administration. The regulatory models adopted by regulating agencies are focused on obtaining results, by allowing administrative entities to elaborate standards that are far from party/political influences, by virtue of technical specialization and professional management skills in the area of operation.

The normative power of Anvisa for the regulation of vague legal concepts in matters of health, contained in laws, decrees and presidential regulations, is strictly divided into legal acts and administrative acts. Considering the particularity of the matter, Anvisa, in order to become capable of intervening in the sectorized economic activity, performs the functions of an auditing, regulating, promoting and, often, arbitrating entity. The concentration of these capacities is disturbing the full exercise of the regulatory power in its task to find a political solution to concrete problems.

Anvisa was granted legal instruments in order to prevent the non-compliance with health legislation, through Administrative Decree No. 354, of August 11, 2006,[13] which established its internal system. This normative act stipulated that the committee decisions, as well as some other less used regulation acts, with regulatory or interventional purpose, would be denominated as Resolution of the Board of Directors.

The possibility of editing resolutions and other regulations gives the Agency the freedom required for the technical and discretionary activity of the state, to be tackled in an abstract way, since there is no way to establish a method or a predetermined formula valid for all cases. The margin of technical discretion possessed by the public power, in the face of indeterminate legal concepts, is quite broad and can receive a breakdown of acts or recommendations that are not strictly in accordance with the legal provisions for the regulation of the activity. This presupposes, among other forms of action, the issuance of regulatory acts that fulfill the legal purposes.[14]

The extrajudicial technical/scientific matters (statistics, sanitary engineering, biochemistry, etc.) were left by the Federal Legislative Power to the Public Administration, so that the social and economic solutions can be obtained by professionals of specialized knowledge. Thus, the application of technical knowledge and standards, as a requirement for the legitimization of Public Administration in sanitary regulation, must be in line with the efficiency and rationality required by the sector.

These are the elements and criteria of the technical/administrative discretion, which is different from classical discretion. The first one stems from opportunity and convenience, while the second is based on efficiency and reasonableness.[15] Clearly, the application of regulatory measures is preceded by an examination of the discretion and the opportunity that is given to the administrator to decide on a more appropriate solution, aimed at achieving the legal purpose and the satisfactory resolution of a concrete case.[16] Discretion

– como na hipótese dos autos." (BRASIL. Tribunal Regional Federal da primeira região. Apelação Cível 55410620064013503/DF. Processo 2006.35.03.005541-5, Processo Originário 0005541-06.2006.4.01.3503/RVD. Relator: Desembargadora Federal Kassio Nunes Marques. Data da publicação: 08/08/2013. Brasil, 2006c. Available from: <https://is.gd/OJyY9n>. Access on: 30 Jan. 2018).

12 BRASIL. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. *Diário Oficial da União,* Brasília, 26 jan. 1999b. Available from: <http://www.planalto.gov.br/ccivil_03/leis/L9782.htm>. Access on: 20 Feb. 2018.

13 BRASIL. Agência Nacional de Vigilância Sanitária. Portaria nº 354, de 11 de agosto de 2006. Aprova e promulga o Regimento Interno da Agência Nacional de Vigilância Sanitária – ANVISA e da outras providências. *Diário Oficial da União*, Brasília, 2 jan. 2006. Available from: <https://is.gd/7Ea2T4>. Access on: 27 Jan. 2018.

14 PEREIRA NETO, Caio Mário da Silva; PINHEIRO, Luís Felipe Valerim; ADAMI, Mateus Piva. Tráfego mútuo e direito de passagem como instrumentos para compartilhamento de infraestrutura no setor ferroviário. In: SCHAPIRO, Mario Gomes (Coord.). *Direito econômico:* direito econômico regulatório, série GV-law. São Paulo: Saraiva, 2010. p. 207.

15 ELIAS, Alexandre Nemer. *A discricionariedade técnica nos atos administrativos sanitários.* Dissertação – Faculdade de Saúde Pública, Universidade de São Paulo. São Paulo, 2008. Available from: <https://is.gd/zBBYnk>. *Access on: 15 jan. 2018.*

16 GROTTI, Dinorá Adelaide Musetti. A teoria dos conceitos jurídicos indeterminados e a discricionariedade técnica. *Revista*

shall continue in cases that contain a legal framework, which allows the manager freedom of action and, therefore, does not arise from the technical character of the matter.

The definition, clarification and interpretation of vague legal concepts, according to the administrative bibliography, cannot alter the legal/sanitary order and must be based on the common sense, morality and efficiency of the act, that is, they must be in agreement with the technical/administrative measure of discretion (normative).

In the exercise of their normative power, stemming from their own supervisory competency, regulatory agencies, in addition to not being able to make changes in the legal order in absolute terms, nor can they create or apply penalties which are not foreseen in a prior law or that are contrary to the law, or penalties that determine the change of status of the people and impose restrictions on liberty, equality or property.[17] Otherwise, collective decisions are limited to improving, enforcing or making the rule provided by law to apply on an individual basis.

The limit of the agencies' regulatory acts must comply with the principle of proportionality, by counterbalancing the fundamental rights with the protected public interest, a classic notion that goes beyond the supremacy of the health authority. Leuzinger and Santana consider that the Brazilian normative acts that deal with the freedom of speech in case of collision with other constitutional principles apply to the weighting technique, consequently, the freedom of speech may cease to prevail.[18]

In this regard, fundamental rights serve as an evaluative parameter to avoid the abuse of the regulatory power of agencies, which must always safeguard the supremacy of the public interest.[19] As Pertence and Barroso explain, "the result of the restrictive measure imposed by Anvisa, in fact, means the extinction, without any constitutional or legal basis, of the production and trade of tobacco products in the national territory as it exists today."[20]

Based on the hermeneutics of comparing public interest with the individual interests of those whose rights were affected, Anvisa's performance must be evaluated through its choices and informed by technical criteria of proportionality (necessity for the measure and suitability of the medium) between the supremacy of the public interest and the fundamental rights. With regard to regulatory sanitary production, the resolutions issued by the agencies have their validities tied to harmony with the major legal norms and in compliance with them.

Due to the increase in the technical character of the state administrative activity, the establishment of limits for technical discretion is accepted and is divided into instrumental legal/technical discretion, based on the purely interpretative activity of the administrator, and technical/administrative discretion in which there is freedom of choice regarding the preparation of regulatory norms and the resolution of the specific case.

Therefore, the standardization created by Anvisa is sheltered by technical discretion. Thus, the Judiciary is not authorized to intervene in the convenience and opportunity of the acts of this Agency as recorded in the jurisprudence of the Superior Court of Justice:

Direito UFMS, Campo Grande/MS, Edição Especial, p. 165-185, jan./jun.2015. Available from: <http://seer.ufms.br/index.php/revdir/article/view/1238>. Access on: 7 Dec. 2017.

17 ARAGÃO, Alexandre Santos de. *Agências Reguladoras e a Evolução do Direito Administrativo Econômico.* 3. ed. Rio de Janeiro: Forense, 2013. p. 452.

18 LEUZINGER, Márcia Dieguez; SANTANA, Paulo Campanha. Liberdade de expressão no Brasil: Princípio ou regra, na perspectiva conceitual de Robert Alexy? *Cadernos de Dereito Actual*, n. 8, p. 103-114, 2017. Available from: <https://is.gd/LyzyEC>. Access on: 07 Apr. 2018.

19 WACHELESKI, Marcelo Paulo. Supremacia do interesse público, direitos fundamentais e a proporcionalidade nos atos das Agências Reguladoras. *Revista Jurídica da Presidência,* Brasília, Edição Comemorativa 17 anos. p. 226. Available from: <http://dx.doi.org/10.20499/2236-3645.RJP2016v0e0-1455>. Access on: 29 Dec. 2017.

20 PERTENCE, Sepúlveda; BARROSO, Luís Roberto. Resolução da ANVISA que proíbe o uso nos cigarros de ingredientes que não oferecem risco à saúde. *Revista de Direito Administrativo*, Rio de Janeiro, v. 269, p. 306, maio/ago. 2015. Available from: <http://dx.doi.org/10.12660/rda.v269.2015.57603>. Access on: 15 Dec. 2017.

> regarding the alleged illegality in the public cost of treatment that is not recognized by Anvisa, the decision under review is based on constitutional interpretation: in the extension of the clauses concerning assertion of the fundamental right to life, health and the principle of the dignity of the human person. Confirm the following excerpt from the ruling of the judgment (242/243): "I note that the prerogative of the State in assessing the material viability, convenience and opportunity to establish its administrative priorities as well as in the way to achieve them, is a matter for which the public entity enjoys a certain discretion, and there is no interference of the Judiciary at this point. However, this prerogative does not lend itself to eliminating the obligatory nature of the benefit, on the grounds that the medication is not on the standardized list of the Health System.[21]

Anvisa acts on the basis of the constitutional provision of state health protection, described in art. 196. In order to establish its competence to regulate, in the meantime, it has also invoked other constitutional rules to, by expansion, deal with other matters of equal substantive value. As an example, Anvisa has prevented legal entities from making certain advertisements, under the argument of protecting health (prevention and control of chronic non-communicable diseases, in line with the practice of the World Health Organization), as provided in the Resolution of the Board of Directors RDC No. 24 of June 15, 2010.[22] Such legislation has restricted commercial advertising of foods containing high levels of saturated/genetically modified fats, sodium/sugar and low nutritional drinks etc., although the Constitution refers strictly to alcoholic beverages, therapies, medicines and tobacco, according to the list set forth in §3 and §4 of art. 220 of the Constitution.

3. Is Anvisa's regulatory competence different?

It is known that the public policies of the regulatory agencies proposed by the government should be in line with what the Executive and Legislative Powers establish. Thus, in order to ensure the achievement of the objectives outlined in the essential acts and safeguarding this necessary harmony of its actions with the agenda and the sector policy, the autarchies adopted the ministerial supervision provided for in art. 26 of Decree Law No. 200/1967in lieu of the hierarchical subordination to the direct Administration.

Specifically, Anvisa is being overseen by the Ministry of Health – with an area of expertise in the Public Health System (SUS) and as a member of the National Health Surveillance System –, which does not interfere with the autonomy expected for the Agency. In this case, ministerial supervision is a conforming instrument, which avoids decoupling of the public health policies and the institutional purposes of the supervisory body.

The controversy revolves around the use by the regulated sector of an improper hierarchical appeal directed towards the Ministry of Health, due to final decisions taken by the supervised agencies. One of the characteristics of the special regime of regulatory agencies refers to the definitive character of their final decisions, and the impropriety of this legal mechanism that could only be removed by a formal law, *stricto sensu*.

21 In the original: "quanto ao tema da suposta ilegalidade no custeio público de tratamento que não é reconhecido pela ANVISA, a decisão atacada está arrimada em interpretação constitucional: na extensão das cláusulas assecuratórias do direito fundamental à vida, à saúde e do princípio da dignidade da pessoa humana. Confira-se o seguinte trecho do voto condutor do acórdão (fls. 242/243): "Anoto que a prerrogativa do Estado na avaliação da viabilidade material, conveniência e oportunidade para estabelecer suas prioridades administrativas bem como a forma de alcançá-las é matéria para a qual o ente público goza de certa discricionariedade, não havendo, neste ponto, a ingerência do Poder Judiciário. Entretanto, tal prerrogativa não se presta a afastar a obrigatoriedade da prestação, sob o argumento de a medicação não constar da lista padronizada do Sistema Único de Saúde." (BRASIL. Superior Tribunal de Justiça. *Processo AREsp 472738*. Relator: Ministro Benedito Gonçalves. Data da publicação: 18 fev. 2014. Available from: <https://is.gd/8UmI8e>. Access on: 10 jan. 2018).

22 BRASIL. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada – RDC nº 24, de 15 de junho de 2010. Dispõe sobre a oferta, propaganda, publicidade, informação e outras práticas correlatas cujo objetivo seja a divulgação e a promoção comercial de alimentos considerados com quantidades elevadas de açúcar, de gordura saturada, de gordura trans, de sódio, e de bebidas com baixo teor nutricional, nos termos desta Resolução, e dá outras providências. *Diário Oficial da União*, Brasília, 15 jun. 2010. Available from: <https://is.gd/jGg5Iw>. Access on: 23 Feb. 2018.

On the other hand, Opinion AC-51/2006 of the Attorney General's Office (AGU) presented a different understanding by accepting, in certain situations, the hierarchical appeal to the supervisory ministry of the regulatory agency. Thus, to this respect we have the following list:

> PORT OF SALVADOR - THC2 (Terminal Handling Charge) - DECISION OF ANTAQ (National Agency of Waterways Transport). REGULATORY AGENCY. KNOWLEDGE AND PROVISION OF IMPROPER HIERARCHICAL APPEAL BY THE MINISTRY OF TRANSPORT. MINISTERIAL SUPERVISION. INSTRUMENTS. ADMINISTRATIVE REVIEW. LIMITATIONS. (I) The President of the Republic, for any relevant public interest reason, may appeal and decide on any matter within the scope of the Federal Administration, (DL nº 200/67, article 170). (II) The decisions of the regulatory agencies regarding their administrative activities or those exceeding the limits of their substantive capacities as defined by law or regulation, or violate the public policies defined for the sector regulated by the Direct Administration, are subject to ministerial review, ex officio or through challenge by the interested parties, including by presentation of an improper hierarchical appeal. (III) Exceptionally, in the absence of a mechanism for the ministerial administrative review, an improper hierarchical appeal to the supervising Ministries cannot be lodged against final decisions of the regulatory agencies which were adopted in the strictest scope of their regulatory capacities as provided by law and that are appropriate for the defined public policies of the sector. (IV) In the case under analysis, the decision adopted by ANTAQ must be maintained because it affects the competency in its area of final responsibility, and it is unacceptable, in the present case, the provision of an improper hierarchical appeal for the review of the Agency's decision by the Ministry of Transport, leaving without effect the ministerial approval of Opinion CONJUR/MT 244/2005. (V) The coordination of the Federal Attorneys' Offices together with the regulatory agencies, by the Legal Advisory is not extended to the decisions adopted by these entities of the indirect Administration when referring to the regulatory competencies of these entities as specified in law. For this purpose, it would have been derived from the power of the ministerial review, which, if exceptionally absent in the circumstances previously explained, also removes the powers of the Legal Advisory. The same applies in relation to the linking of regulatory agencies to ministerial opinions, which are not being obliged to review their decisions in order to execute them, as well as in exceptional circumstances, provided that they are within the same scope of the regulatory action. (VI) In the event of dispute between Ministries and the regulatory agencies regarding the determination of their competencies, or even divergence of duties between a regulatory agency and another entity of the indirect Administration, the matter shall be submitted to the Union's Attorney General. (VII) The regulatory guidelines of the UAG bind the regulatory agencies. VIII - The regulatory agencies must adopt all measures to ensure that, except for those cases provided for by law, no agent that is not a carreer Federal Prosecutor may perform any of the duties provided for in article 37 of MP (Provisional Measure) No. 2.229-43/2001.[23]

23 In the original: "PORTO DE SALVADOR. THC2. DECISÃO DA ANTAQ. AGÊNCIA REGULADORA. CONHECIMENTO E PROVIMENTO DE RECURSO HIERÁRQUICO IMPRÓPRIO PELO MINISTÉRIO DOS TRANSPORTES. SUPERVISÃO MINISTERIAL. INSTRUMENTOS. REVISÃO ADMINISTRATIVA. LIMITAÇÕES. I - O Presidente da República, por motivo relevante de interesse público, poderá avocar e decidir qualquer assunto na esfera da Administração Federal- (DL nº 200/67, art. 170). II - Estão sujeitas à revisão ministerial, de ofício ou por provocação dos interessados, inclusive pela apresentação de recurso hierárquico impróprio, as decisões das agências reguladoras referentes às suas atividades administrativas ou que ultrapassem os limites de suas competências materiais definidas em lei ou regulamento, ou, ainda, violem as políticas públicas definidas para o setor regulado pela Administração direta. III - Excepcionalmente, por ausente o instrumento da revisão administrativa ministerial, não pode ser provido recurso hierárquico impróprio dirigido aos Ministérios supervisores contra as decisões das agências reguladoras adotadas finalisticamente no estrito âmbito de suas competências regulatórias previstas em lei e que estejam adequadas às políticas públicas definidas para o setor. IV - No caso em análise, a decisão adotada pela ANTAQ deve ser mantida, porque afeta à sua área de competência finalística, sendo incabível, no presente caso, o provimento de recurso hierárquico impróprio para a revisão da decisão da Agência pelo Ministério dos Transportes, restando sem efeito a aprovação ministerial do Parecer CONJUR/MT nº 244/2005. V - A coordenação das Procuradorias Federais junto às agências reguladoras pelas Consultorias Jurídicas dos Ministérios não se estende às decisões adotadas por essas entidades da Administração indireta quando referentes às competências regulatórias desses entes especificadas em lei, porque, para tanto, decorreria do poder de revisão ministerial, o qual, se excepcionalmente ausente nas circunstâncias esclarecidas precedentemente, afasta também as competências das Consultorias Jurídicas. O mesmo ocorre em relação à vinculação das agências reguladoras aos pareceres ministeriais, não estando elas obrigadas a rever suas decisões para lhes dar cumprimento, de forma também excepcional, desde que nesse mesmo âmbito de sua atuação regulatória. VI - Havendo disputa entre os Ministérios e as agências reguladoras quanto à fixação de suas competências, ou mesmo divergência de atribuições entre uma agência reguladora e outra entidade da Administração indireta, a questão deve ser submetida à Advocacia-Geral da União. VII - As orientações normativas da AGU vinculam as agências reguladoras. VIII - As agências reguladoras devem

Under the terms of the previously mentioned opinion, an improper hierarchical appeal is possible, to the disadvantage of the decisions of the Board of Directors (Dicol) of the regulatory agencies, when these distance themselves from the regulatory competency of the common regulating activities, established by law, and are contrary to the public policies defined for the regulated sector.

The distinction between regulatory activities and the administrative competencies of the regulatory agencies intends to maintain the regulatory autonomy owing to the lack of constitutional provisions.[24] Exceptionally, Anvisa holds a legislative delegation allowing it to establish the list of narcotics for criminal purposes. This authorization is limited to complementing the law by improper means through Resolution of the Board of Directors.

It should be noted that, as regards to the regulatory function, there is no legislative delegation, since the delegation is rejected, but at the same time, the normative power is accepted to extend the regulatory power.[25] The delegation of merely preparatory acts for the exercise of police power is acceptable, but not so for the functions of legislation and enforcement of sanctions to a legal entity under private law. Based on this premise, constitutional rules do not allow the recognition of a different modality of legislative delegation in the regulation, in other words, the existence of a regulation as the primary source of law, except for the restricted hypothesis of the only example of the autonomous regulation, according to art. 84, VI, of the Federal Constitution.[26]

For political expediency of the moment, the legislator may disengage himself from his power/duty of legislating on a sensitive subject, in order to enable the approval of a legal regulation that is still without consensus. The double renunciation of the Legislative and Executive permits the interpretation of legal rules – containing vague, indeterminate or imprecise legal concepts – by a third party agent. In fact, public policies are practiced by issuing general norms, often with technical indeterminations that require more than a mere process of integration of the legal norms (analogy and general principles of law).[27]

The double renunciation is evaluated by the success or failure of this option in the field of political risk. The regulatory waiver may be an inappropriate option to maintain the constitutional order, in the case of the conflict is postponed or delayed and gets out of control, likewise the success of the double waiver result in slowing down the association in the regulated sector. The sectored conflicts may derive from the regulatory action of the State, which grants public values – on behalf of the interests of the society – to the regulated sector, which tends to the exclusive search for the profit. Thus, they involve an antagonism between the public interest (manifested by its policy in the sector) and a random resistance of the regulated ones.[28]

On the other hand, the 1988 Constitution itself expressly limited the normative power of the external bodies to the Legislative Branch, according to art. 25 of the Transitory Constitutional Provisions Act. In

adotar todas as providências para que, à exceção dos casos previstos em lei, nenhum agente que não integre a carreira de Procurador Federal exerça quaisquer das atribuições previstas no artigo 37 da MP nº 2.229-43/2001." (BRASIL. Advocacia-Geral da União. *Parecer nº AC - 051/2006*. Processo nº 50000.029371/2004-83. Interessado: Ministério dos Transportes. Assunto: Deliberação da ANTAQ. Agência Reguladora. Competência e recurso hierárquico impróprio. Divergência entre o Ministério e a Agência. Brasil, 2006c. Available from: <http://www.agu.gov.br/atos/detalhe/8453>. Access on: 30 Jan. 2018).

24 SANTOS, Murillo Giordan. Agência Nacional de Vigilância Sanitária: ANVISA: Comentários à Lei nº 9.782/99 e ao Decreto nº 3.209/99. In: NOHARA, Irene Patrícia; MORAES FILHO, Marco Antonio Praxedes de. *Coleção direito administrativo positivo*, v. 15. São Paulo: Atlas, 2015. p. 50.

25 ROCHA, Jean-Paul Veiga. Quem tem medo da delegação legislativa? *Revista de Direito Administrativo,* Rio de Janeiro, v. 271, p. 202, jan./abr. 2016. Available from: <http://dx.doi.org/10.12660/rda.v271.2016.60765>. Access on: 23 Dec. 2017.

26 SILVA, Almiro Regis Matos do Couto e. A administração direta e as autarquias especiais, agências reguladoras e agências executivas. In: MODESTO, Paulo (Coord.). *Nova organização administrativa brasileira*. Belo Horizonte: Fórum, 2009. p. 51.

27 GUERRA, Sérgio. Regulação e maleabilidade normativa à luz do direito administrativo econômico. In: FREITAS, Daniela Bandeira de; VALLE, Vanice Regina Lírio do (Coord.). *Direito Administrativo e Democracia Econômica*. Belo Horizonte: Fórum, 2012. p. 243.

28 DELGADO, Joedson de Souza. Regulação sanitária: atribuição da Agência Nacional de Vigilância Sanitária em prol da saúde pública. *Direito e Desenvolvimento*, João Pessoa, v. 6, n. 12, 2015, p. 111. Available from: <https://is.gd/3XPiPA>. Access on: 11 June 2018.

fact, the intention of the authors of the Constitution was to preserve the legislative competence, which, in the post-dictatorship period, would be necessary for redemocratization. The authors of the Constitution also intended, at a later stage, to be able to delegate, precisely, the regulatory power, without causing the suspension of the legal system and without impeding the dialogue necessary for the production of norms by the Legislative.

The law delegated to the Executive is of the same level as an ordinary law and, for that reason, its disrespect is subject to the concentrated constitutional control, including the Parliament's authorizing resolution. However, this constitutional instrument is unusual, since the issuance of provisional measures filled the gaps in regulatory competence, given the ease of its approval process, when compared to that of the delegated law.

In the Brazilian configuration, the control of the regulation exercised by the Legislative is smaller in relation to the predominance of the Executive, which draws attention to the subjects dealt with in the regulatory sphere. Similarly, Anvisa's regulatory performance comes, legitimately, from the overall delegation of the Legislative Branch. This situation may be observed in the authorization given by the Legislative to the President of the Republic, when requested to have a portion of delegated power in the terms desired by the Constitutional Text and within the limits laid down in it. The National Congress, in turn, may stipulate deadlines and detail the conditions of such delegation.

Once the delegated law has been issued, it is constituted as ordinary law within the legal framework and the grant conferred by the Congress to the President ceases. However, the power delegated to it remains. At any time, the Parliament may draw up a new law amending or repealing the matter set forth in the delegating law in force, except in cases where the initiative to propose the matter is reserved for the Executive.

On the other hand, the Congress may authorize, by law, certain public institutions to regulate specific matters in the terms they wish. With this approach, the Congress has a permanent mandate, and can modify the matter a posteriori, as it pleases. In other words, it can change and bring material rules and other procedures adjusted to the agencies, such as reducing the delegated competence or even eliminating it by law. Thus, there are no limits to the Legislative Power, especially if the Constitution does not manifest itself over them.

The same reasoning is used when a later law annuls a regulation that interferes with the constitutional jurisdiction of the Legislative. In any case, the Legislative cannot intervene, by means of any subsequent law, in order to modify the extension of the delegation given to an administrative body that, e.g. exceeds what is provided for in the Constitutional Text or encroaches state regulatory authority.

However, the two situations described allow the discussion about the permanence of the effects as an acquired right and as a perfect judicial act. In any case, the Legislative Branch can revoke the delegation, when determining any vices of unconstitutionality. What about Parliament's constitutional competence with regard to constitutional amendments 8 and 9? Such constitutional amendments do not relate to the institutional allocations of Anatel (National Telecommunications Agency) and ANP (National Petroleum Agency). They only foresee them and therefore do not exhaust the power of the Legislative to edit any subsequent law restricting or annulling any extension of the legislative delegation brought about by the amendments that have encroached on the exclusive competence of the Federal Executive Branch (President and Ministers).

This legislative amendment is a kind of political control that focuses on the functioning of the regulatory bodies.[29] In general, the model of sanitary legislation production tends to be relaxed in the relationship between State and society, aiming at adjusting the public power as a result of this new reality. Moreover, in

29 GALVÃO, Gabriel de Mello. *Fundamentos Limites da Atribuição de Poder Normativo às Autarquias Autônomas Federais (Agências Reguladoras)*. Rio de Janeiro: Renovar, 2006. p. 160.

certain matters, however, only the formal law allows restrictions in the performance of the institution or administrative entity, based on the purposes that are to be achieved or in the means that must inevitably be adopted by the legislator.[30]

In such case, the regulatory power of the agencies is subject to internal and external probes on the legality of the acts, just as individuals have the guarantee of legal reserve (or strict legality) against abuses of the Public Administration, when it intends to attack he fundamental rights. The broad control over the concession of normative power to agencies encompasses the constitutionality control (concentrated control and diffused control), the control in the exercise of normative power (suspension of regulatory acts by the Legislative Power and jurisdictional control in the exercise of normative power), the improper control of the exercise of the normative power (functions of the Executive Branch and functions of the Legislative Branch).

Therefore, the federal regulatory agencies are subject to the legislative control of the National Congress through the supervision ex ante (previous inspection) and supervision ex post (a posteriori inspection). There is practically no supervision ex ante by the Federal Legislative in the activity and means of the verification of the articles of law related to the structure of the agencies and to their mechanisms; and the second one, by the sanction of the action of the agencies, such as the control of the legislative agenda, including contingency budgets and nominations of political nominees.

The modification rule of the regulatory acts produced by the agencies is the supervision ex post, and regulatory for its lacking of institutional routine of analysis. The parliamentarians, in practice, consider important only the acting of the agencies when they are provoked by a wide media promotion.

In the day-to-day there has not been the exercise of the supervision ex post by the Parliament – which may have two causes.[31] The first of them is the discharge of the agencies of presenting, before the issuance of the norm, studies of the Analysis of Regulatory Impact (AIR) or, later, under the normative text accompanied by the data of the Assessment of Regulatory Result (ARR) that guided/subsidized the decision making. And the second one applies to the unavailability of perennial technical support of orientation to congressmen in the analysis of these norms.

Thus, federal regulatory agencies are subject to legislative control by the National Congress through ex ante and ex post supervision. The first, through verification of the articles of law concerning the structure of the agencies and their mechanisms, and the second, by sanctioning the agencies' actions, such as the control of the legislative agenda, including contingent budgets and appointments of political nominees.

The Executive Branch has delegated powers to regulatory agencies, but in order to carry out their actions, they must have at least access to funds raised through their own sources, duly approved by the Legislative. In turn, the partial release to spend depends on the government and varies from 100% – with salary expenses and continued provision of benefits – down to 0% – with amendments by parliamentarians not aligned to the government.[32] Due to these challenges, the governing law of the agencies, on the basis of open guidelines, established its subordination to the public policies established by the Executive and Legislative branches in order to respond to the relevant purposes of each regulated subject, without being completely isolated from the policy that in fact depends on regulation by presidential decree.

The dormant as well as the potential legislative changes in the status quo of the agencies refer to the

30 BINENBOJM, Gustavo. *Agências Reguladoras, Legalidade e Direitos Fundamentais*: limites aos poderes normativo e sancionatório da ANVISA na regulação de produtos fumígenos. E-gov: Portal de e-governo, inclusão digital e sociedade do conhecimento, 2016. Available from: <https://is.gd/CvC0ae>. Access on: 11 Feb. 2018.

31 ARAÚJO, Luiz Eduardo Diniz. O controle das agências reguladoras pelo Poder Legislativo.*Revista de informação legislativa*: *RIL*, v. 55, n. 217, p. 216, jan./mar. 2018. Available from: <https://is.gd/lB7bOf>. Access on: 16 June 2018.

32 FRANCO, Gustavo H.B. *As leis secretas da economia*: revistando Roberto Campos e as leis do Kafka. Rio de Janeiro: Zahar, 2013. p. 124.

congressional influence in the process of appointment of managers, who must be aligned to their preferences. Also, in the definition of the budget, so that they may or may not program public policies, or in the enactment of amending laws on personnel policy (e.g by dismissing their managers or simply by not sufficiently fulfilling the staff in order to weaken them) or to shape the agency (even to terminate it).[33] Such measures put pressure on regulating agencies to set performance standards by matching their programs with their purpose.

In addition, the proper compliance with the law in favor of legal and democratic control, may cause the actions of a particular agency to inflict discontent with the electorate. In general, the more the content of the regulation impacts the electorate or the campaign financier, the greater the attention of politicians on the agency (public exposure) and therefore, the greater their influence on it (risk of political manipulation).[34] For that reason, as a control tool, the legislative veto allows the Congress to review or annul a norm before it enters into force or that a budget authorization determine a maximum amount of expenses for the activities of the agencies.[35]

The game of interests that can influence the regulatory action reveals the drawbacks of this model which managers are forced to satisfy. The decision-making process to conciliate the various interests allows: (1) that parliamentarians transfer responsibility by the public policies; (2) that managers of the regulatory agencies take political decisions, without the need of a political majority, and (3) that technical standards are formulated and applied under the responsibility of the same institution. This situation endangers fundamental rights.[36]

Indeed, the legislative solution for the normative set of rules of regulatory agencies demonstrates the vibrancy of relations between regulatory agencies and political bodies in the face of outstanding decisions on sectorial public policies. The support of the parliamentarians to the President is fruit of coalition presidentialism, that allows it to act unilaterally, in the agencies.

It is noted that the bargaining process is fundamental in providing political support to government agencies as well as support and injunction of the regulation.[37] Bargaining stems from the difficulty of having a consensus on a subject due to the political pluralism, so, negotiation becomes necessary in order to influence the final decision making.

By considering the recurrent economic and political instabilities the country has suffered, as well as the complexity of interests of the sectors and regulated activities, the disagreements between the agencies and the Congress or the Executive itself must be included. It is natural that any regulation perfected by the agencies becomes part of the regulated sector, separated from the interests of the state and the consumers, since a specific technical choice seeks, above all, efficiency, regardless of bringing any social benefit to the consumer or favoring any governmental policy that serves the public interest.

In many cases, Anvisa has fostered a legislative innovation which not only restricts rights, but also viola-

33 PRADO, Mariana Mota. Uma perspectiva comparada da teoria do domínio presidencial: a relação entre o Poder Executivo e as agências reguladoras no Brasil. *Revista de Estudos Empíricos em Direito.* Dossiê Especial, v. 3, n. 2, p. 78, jul. 2016. Available from: <http://dx.doi.org/10.19092/reed.v3i2.126>. Access on: 7 jan. 2018.

34 CAMPOS, Anna Maria; AVILA, Jorge Paula Costa; SILVA JÚNIOR, Dércio Santiago da. Avaliação de agências reguladoras: uma agenda de desafios para a sociedade brasileira. *Revista de Administração Pública,* Rio de Janeiro, v. 34, a. 5, p. 36, set./out. 2000. Available from: <https://is.gd/G7NUei>. Access on: 12 Feb. 2018.

35 CASTRO JÚNIOR, Osvaldo Agripino de. Aspectos jurídicos destacados dos controles e elementos determinantes da regulação dos transportes aquaviários e portos nos Estados Unidos e Brasil. In: CASTRO JÚNIOR, Osvaldo Agripino de; PASOLD, César Luiz (Coord.). *Direito portuário, regulação e desenvolvimento*. 2. ed. Belo Horizonte: Fórum, 2011. p. 248.

36 SCHOENBROD, David. *Power without Responsibility*: how Congress abuses the people through Delegation. New Haven: Yale University Press, 1993. p. 385-385

37 CAMPOS, Anna Maria; AVILA, Jorge Paula Costa; SILVA JÚNIOR; Dércio Santiago da. Avaliação de agências reguladoras: uma agenda de desafios para a sociedade brasileira. *Revista de Administração Pública*, Rio de Janeiro, v. 34, a. 5, p. 37, set./out. 2000. Available from: <https://is.gd/G7NUei>. Access on: 12 Dec. 2017.

tes the absolute legal reserve, set forth in the Federal Constitution, under the administrative consideration of protecting the public health. Whereby, Anvisa and the other regulatory agencies, in various threshold cases, have advanced in relevant matters to society, which were nevertheless reserved to the congress.

Sensitive matters relating to health surveillance affecting social life must be subject to the democratic decisions of the citizens, represented by the legislator, since they promote welfare and the realization of fundamental rights. This assertion does not indicate totally political judgments unrelated to technical content.

Thus in the dynamics of the capitalist economy, it was possible to adapt the legal norms, so that the Executive could be given greater freedom to issue norms that are complementary to the law. The legal literature supports the issuance of authorized regulations – wrongly termed as delegated regulations –, in which the law sets out only the general principles that ought to be followed by the administrative authority in the specific subject.[38]

In particular, Anvisa, like any other regulatory agency, has no margin of freedom to discuss, in technical terms, matters that go beyond the mere technical and sectorial regulation under penalty of having them considered unconstitutional.

It is understood that the regulation disseminated on the Constitutional or Legal Text, or on Legislation, even if apparently incomplete, should not suffer abuse and excesses due to the regulatory choices (convenience and opportunity) of the health entity, whose interference may impede the exercise of the economic activity, with the removal of its administrative legitimacy. Due to the system of law, the standardization of health surveillance actions regulates all economic activities through orders issued by the state power. Otherwise, the individual rights would be dependent on the will of the state, which could possibly draw upon other illegitimate interests.

It is also known that the regulatory power of the Administration envisages two literary currents. In particular, in the state penalties area, which exclusively rests on formal law to determine infractions and establish administrative penalties. Another minority aspect is that administrative infractions should be set out in a regulation, by means of the prediction of weighing criteria, or the determination of aggravating and mitigating factors, while it is for the law to provide for the administrative penalties.[39]

In such cases, the Constitution prescribes that the matter at issue be submitted to the Parliament or to participatory and democratic discussions for the formulation of a specific federal law. The rise of the doctrine of constitutionalism in the eleventh century allowed for the expansion of the idea of freedom, which, in addition to the concept of "not to do", includes a duty of the State towards society.[40]

Hence the reason of the Constitution to choose to grant exclusively to the law some matters relevant to society, something that distances it from the technical, regulatory domain that is related to the police power of the regulatory agencies. The principle of the absolute legal reserve states that only laws issued by the Parliament and sanctioned by the President of the Republic can control the exercise of individual rights, while the principle of the relative legal reserve allows the Executive to complement such actions dedicated to the formal law, through presidential decrees or ministerial ordinances, provided that it does not exceed the limits of the regulating adjustments allowed by the system.[41]

38 BRUNA, Sérgio Varella. *Agências reguladoras*: poder normativo, consulta pública, revisão judicial. São Paulo: Revista dos Tribunais, 2003. p. 67.

39 PALMA, Juliana Bonacorsi de. Regulação e autoridade: o poder sancionador na regulação. In: MEDAUAR, Odete; SCHIRATO, Vitor Rhein (Coord.). *Poder de polícia na atualidade*: anuário do Centro de Estudos de Direito Administrativo, Ambiental e Urbanístico – CEDAU do ano de 2011. Belo Horizonte: Fórum, 2014. p. 95.

40 TEIXEIRA, Anderson Vichinkeski. Direito Público Transnacional: por uma compreensão sistêmica das esferas transnacionais de regulação jurídica. *Revista Novos Estudos Jurídicos*, v. 19, n. 2, p. 406, maio/ago. 2014. Available from: <http://dx.doi.org/10.14210/nej.v19n2.p400-429>. Access on: 20 Dec. 2017.

41 DIAS, Maria Tereza Fonseca; CARMO, Flávia Figueiredo Franco; SIMÕES, Fabiana Coelho. O poder normativo discricionário na atividade regulatória da Agência Nacional de Transportes Terrestres e a ausência de controle jurisdicional. *Revista*

The absolute legal reserve stems from relevant matters, expressly indicated by the Constitution and, therefore, containing administrative restrictions, which must be dealt with by the Parliament through participatory and democratic procedures of debate, agreement, and vote. In short, there is no space for administrative deliberations regarding certain constitutionally anticipated matters, under the penalty of strict violation of the law.

On the other hand, the relative legal reservation allows the supplementing of its forecasts by a regulating act, even though it is a formal law in the strict sense. The relative legal reserve accepts that non statutory acts may regulate certain matters included in law, as long as it does not alter the legal order.[42]

By neither setting goals nor implementing public policies, Anvisa has to use the policy of law formulated by the state political powers – and not the government's own policy or the policy that was implemented on its own. A diverse understanding shows what Law No. 9.782, of 1999[43] points out: "Art. 8º. The Agency is required to, respected the legislation in force, regulate, control, and supervise the products and services involving risk to the public health", since it has already taken a generic position about Anvisa's competence, ratified by the same Legislative with the approval of the Law in question – six years later –, also approved of the Framework Convention on Tobacco Control (CQCT), through the Legislative Decree No. 1.012, of October 27, 2005.[44],[45]

Justice Eros Grau, of the First Panel of the Federal Supreme Court, at the time, incorporated his authoritative opinion, in which he settled between reservation of law (absolute reservation or in a strict sense) and reservation of norm (relative reservation). From his decision, we highlight the following excerpt:

> In fact, by specializing courts and assigning competencies based on the nature of legal facts is not a matter achieved by legal reservation in the strict sense, but only by the principle of legality affirmed in article 5, II of the Brazilian Constitution, that is, by reservation of the norm. Take the wording of the principle: no one will be obliged to do or refrain from doing anything except by the force and terms of the law. There is a clear distinction between the following situations: [i] linkage to the definitions of the law, [ii] linkage to the resulting definitions – i.e. those established by virtue of it – by law. In the first case we are before the legal reservation; in the second, in front of the "norm reservation" [a norm which may be both legal, regulatory or regulating]. In the second situation, even when the definitions in question operate in regulatory acts that are not of the legislative kind – but stemming from an implicit or explicit provision in law – the principle will be duly adhered to. In this case, the principle of legality expresses legal reservation in relative terms [= reservation of the norm]. This is why the exercise of a normative function does not prevent any explicit or implicit assignment to the Executive and the Judiciary to define, in exercising the normative function, obligations of doing or refrain from doing imposed on individuals – and link them. Turning to article 5, II of the Constitutional Text, we find that the principle of legality is taken in relative terms, which leads to the conclusion that the due consideration is given to it when – manifested, expressly or implicitly, assignment for this purpose – normative, non-legislative act, but still a regulatory or procedural one, defines the obligation of "doing or refrain from doing" is imposed to its recipients. Indeed, the constitutional provision at issue enshrines the principle of legality in only relative terms, which in at least three opportunities [i.e. Article 5, XXXIX, Article 150, I and the Sole Paragraph of Article 170], the Constitution resumes the principle, then adopting it in absolute

Meritum, Belo Horizonte/MG, v. 12, n. 2, p. 221, jul./dez. 2017. Available from: <http://www.fumec.br/revistas/meritum/article/view/5711>. Access on: 21 Feb. 2018.

42 DEÁK, Renato Albuquerque; NOBRE JÚNIOR, Edilson Pereira. O princípio da legalidade e os limites do poder regulamentar. *Revista Acadêmica da Faculdade de Direito do Recife*, v. 89, n. 01, p. 160, 2017. Available from: <https://periodicos.ufpe.br/revistas/ACADEMICA/article/view/229465>. Access on: 11 Feb. 2018.

43 BRASIL. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. *Diário Oficial da União*, Brasília, 26 jan. 1999b. Available from: <http://www.planalto.gov.br/ccivil_03/leis/L9782.htm>. Access on: 20 Feb. 2018.

44 BRASIL. *Decreto Legislativo nº1.012, de 27 de outubro de 2005*. Aprova o texto da Convenção-Quadro sobre Controle do Uso do Tabaco, assinada pelo Brasil, em 16 de junho de 2003.Diário da Câmara dos Deputados, Brasília, 18 set. 2003. Available from: <https://is.gd/wXoE3k>. Access on: 12 June 2018.

45 SILVA, Afonso Virgílio da. Anvisa e o controle do tabagismo. *Revista de Direito Administrativo*, Rio de Janeiro, v. 268, p. 325-326, jan./abr. 2015. Available from: <http://dx.doi.org/10.12660/rda.v268.2015.50742>. Access on: 27 Dec. 2017.

> terms [...] Had not Article 5, II enshrined the principle of legality in only relative terms and reasoning, its insertion in the core of the Constitution, in such absolute terms, would not be justifiable in those cases. To put it another way: if there is already a principle of legal reservation –, i.e. if there are matters that cannot be regulated except by the law, it is evident that the Executive and the Judiciary Branches can deal with the excluded ones, stating about them, in regulations and regiments.[46]

The delegitimization conducted by the regulatory agencies involves an interpretative effort of these factual situations under the command of the jurisdictional control of the Legislative, the Judiciary and the Executive, the latter referring to the non-delegable competencies. Therefore, the administrative option by Anvisa should make the operationalization of the ordinary norm (law) compatible, and not create it with a view to its greatest efficiency.

Anvisa, when making a decision that does not comply with assumptions of a certain legal procedure – which, in turn, is not defined in the law –, will create a dispute which will be submitted to the Judiciary. In this respect, some authors believe that an excessive limitation of the regulatory activity may affect the democratic constitutional state, since the editing of the normative act should balance out the Central Government's policy actions.

As it became clear, Anvisa has often altered the legal order with its non-statutory legislation, issued by Resolution of the Board of Directors. Thus it has allowed an erosion of the principle of legality, which infringes upon individual rights when interpreting or explaining vague concepts of a technical nature contained in the laws. In this regard, researchers schematized the main actions related to the prohibition of additives in tobacco products in Brazil, the reactions of the groups of interest and of the productive sector, and the convoying taken until the beginning of 2014.[47],[48]

Anvisa, in particular cases, has replaced the legislator, with the embodiment of secondary rules through ordinances and resolutions, something that causes concern, given the economic and legal insecurity of the regulated environment. In other cases, Anvisa has bypassed the statutory law by incorporating an additional regulatory delegation.

46 In the original: "Com efeito, especializar varas e atribuir competências por natureza de feitos não é matéria alcançada pela reserva da lei em sentido estrito, mas apenas pelo princípio da legalidade afirmado no artigo 5º, II da Constituição do Brasil, ou seja, pela reserva da norma. Tome-se o enunciado do preceito: ninguém será obrigado a fazer ou deixar de fazer alguma coisa senão em virtude de lei. Ora, há visível distinção entre as seguintes situações: [i] vinculação às definições da lei; [ii] vinculação às definições decorrentes – isto é, fixadas em virtude dela – de lei. No primeiro caso estamos diante da reserva de lei; no segundo, em face da "reserva de norma" [norma que pode ser tanto legal quanto regulamentar; ou regimental]. Na segunda situação, ainda quando as definições em pauta se operem em atos normativos não da espécie legislativa – mas decorrentes de previsão implícita ou explícita em lei – o princípio estará sendo devidamente acatado. No caso, o princípio da legalidade expressa reserva da lei em termos relativos [= reserva da norma], razão pela qual não impede a atribuição, explícita ou implícita, ao Executivo e ao Judiciário, para, no exercício de função normativa, definir obrigações de fazer e não fazer que se imponham aos particulares – e os vincule. Voltando ao artigo 5º, II do texto constitucional, verificamos que, nele, o princípio da legalidade é tomado em termos relativos, o que induz a conclusão de que o devido acatamento lhe estará sendo conferido quando – manifesta, explícita ou implicitamente, atribuição para tanto – ato normativo não legislativo, porém regulamentar ou regimental, definir obrigação de fazer ou não fazer alguma coisa imposta a seus destinatários. Tanto isso é verdadeiro – que o dispositivo constitucional em pauta consagra o princípio da legalidade em termos apenas relativos – que em pelo menos três oportunidades [isto é, no artigo 5º, XXXIX, no artigo 150, I e no parágrafo único do artigo 170] a Constituição retoma o princípio, então o adotando em termos absolutos (...). Não tivesse o artigo 5º, II consagrado o princípio da legalidade em termos somente relativos e razão não haveria a justificar a sua inserção no bojo da Constituição, em termos então absolutos, nas hipóteses referidas. Dizendo-o de outra forma: se já um princípio de reserva da lei – ou seja, se há matérias que não podem ser reguladas senão pela lei – evidente que das excluídas a essa exigência podem tratar, sobre elas dispondo, o Poder Executivo e o Judiciário, em regulamentos e regimentos." (BRASIL. Supremo Tribunal Federal. *Habeas Corpus nº 85.060/PR*. Relator Ministro Eros Grau. Brasília, 13 fev. 2009. Diário de Justiça Eletrônico. Available from: <https://is.gd/RKgGj8>. Access on: 23 Feb. 2018).

47 TURCI, Silvana Rubano Barretto; FIGUEIREDO, Valeska Carvalho; COSTA E SILVA, Vera Luiza da. A regulação de aditivos que conferem sabor e aroma aos produtos derivados do tabaco no Brasil. *Cadernos Ibero-Americanos de Direito Sanitário*, Brasília, DF, v. 3, n. 1, p. 55-59, jan./jun. 2014. Available from: <http://dx.doi.org/10.17566/ciads.v3i1.18 Access on: 11 June 2018.

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4. External control by the judiciary

Anvisa has implemented adjustments by Resolution of the Board of Directors, based on its regulatory power. However, in their respective spheres of activity, the Powers believe that Anvisa, in certain situations, has created primary rules, going contrary to established laws, such as in its interference with the regulating of smoke products. In any case, Anvisa is at the center of a controversy regarding its regulatory actions.

It is pointed out that Anvisa's technical/regulatory decisions incorporate a political decision making, with a predominance in technical matters, conducted by specialized public agents and in direct contact with the issues that should be regulated. In this context, the technical expertise of the regulatory body emerges. This serves as a means (technical choices) to achieve the goal (establishment of sectorial policies, definition of objectives and priorities) determined under the guidance of the political powers.

Anvisa's jurisdictional control over the exercise of the normative power presents itself as a secondary option, which is carried out only in a diluted form, subsequent to the issuance of the regulatory act. This may have as parameters: the principles of the law (control of legality), which is decided by the common courts; or what is determined under the Constitution (constitutional control), decided by the Federal Supreme Court, when the technical matter of merit is broad (vague) and constitutional. When the matter is unclear, the Judges of the Federal Court may also exclude compliance with unconstitutional rules issued by regulatory agencies.

It is a fact that the normative output of the agencies exceeds, in numbers, that of the legislative output. This is something that draws the attention of the Judiciary Power concerning control in the aspects of proportionality, reasonability, legitimacy and legality. In the context of solutions to constitutional conflicts, the judicial control of regulatory competency has a predominant role for the legal certainty of the regulatory activity, especially when the Executive maintains legitimacy in the exercising of the regulatory power in the event of an allegation of excessiveness by those regulated.

There is no need to exhaust the administrative channels for the Judiciary to consider the matter, except for disputes involving the Sports Justice, which must be placed in the highest administrative authority, so that the Judiciary can manifest itself, including about the suitability of habeas corpus in military disciplinary punishments. In view of these considerations, the regulation is subject to judicial determination for possible deviation of powers from the legal norm, something that may be unlawful.

The interference in all levels or instances of the Judiciary may be used for political purposes, in situations such as: (1) granting an injunction that, even when suspended by higher courts, allows for the extension of administrative decisions, (2) embarrassment caused to occupants of public office, (3) knowledge of the author/complainant and delimitation of his position on the political scene, and (4) filling gaps left by the Parliament.[49] As a result of the crisis of the law, judicial protagonism/activism is a response to the exorbitance of the regulatory power in the field of public services.[50]

The conduction of the public policies by the Executive may be interfered with by the court. However, its decision must be guided by the constitutional jurisdiction, in such a way as to limit its action only to what is necessary to maintain the institutional order, safeguarding the autonomy of the agencies.[51] In any case, the current constitutional state prompts a reflection on the role of the law.

49 CADEMARTORI, Luiz Henrique Urquhart;MIRANDA, José Alberto Antunes. O papel regulatório da legislação no Estado Constitucional de Direito. *Conpedi Law Review*, Oñati, Espanha, v. 2. n. 2, p. 404, jan./jun. 2016. Available from: <https://is.gd/UGN5x6>. Access on: 22 Feb. 2018.

50 BICCA, Carolina Scherer. Judicialização da política e ativismo judicial. *Revista de Direito Brasileira,* v. 2, n. 2, p. 138, 2012. Available from: <http://dx.doi.org/10.26668/IndexLawJournals/2358-1352/2012.v2i2.2700>. Access on: 12 Mar. 2018.

51 OLIVEIRA, Kátia Cristine Santos de; COSTA, Jamille Coutinho. Direito à saúde: da (in)efetividade das políticas públicas à sua judicialização como forma de garantir o mínimo existencial. *Revista de Direito Brasileira*, Florianópolis, v. 1, n. 1, p. 96, jan./fev. 2011. Available from: <http://dx.doi.org/10.26668/IndexLawJournals/2358-1352/2011.v1i1.2678>. Access on: 22 mar. 2018.

The solution to this case is also observed in the comparative law. On April 3rd, 2014, the European Parliament and the Council of the European Union issued a Directive 2014/40/EU with the establishment of stricter rules about the trade and consumption of tobacco products that have nicotine to present to the authorities a list of all ingredients contained in them, including the prohibition of certain aromas, except the menthol cigarettes, which can stay for a further eight years (until 2020). It is important to stress that the Directive is a kind of law targeted to the member countries of the European Union, which must decide, individually, according to its reality, if is in accordance with the alterations proposed by the European Commission.

Therefore, the deputies of the European Parliament approved of the Directive 2014/40/EU, but it depends on the approval of the community countries and, by consequence, of the Council in adopting the dispositions and normative conditions in order to meet the goal. By the way, there is the prohibition at European level regarding the use of aromatic and flavored additives added to the smoke products:

> Article 7. The Regulation of the ingredients […] 7. The States Member prohibit the trade of tobacco products containing flavoring in their components, such as filters, papers, package, capsules, or any technical characteristics that enable the modification of the smell or flavor of the tobacco products in question or the intensity of their fume. The filters, papers, and capsules do not have tobacco or nicotine.[52]

As it can be noticed in the legal mechanism previously transcribed, the health norm was issued by the European Parliament and by the Council of the European Union, aiming at dissuading the young people from smoking and at protecting the consumers' health, provided that the European Union and all its Country Members are part of the CQCT.

The following examples demonstrate how the Judiciary reacted to the administrative conduct in matters of fact and of law or public policies, due to arbitrariness and inconsistency of the act that encroached upon the jurisdiction of the Powers.

5. The regulation of additives providing flavor and aroma to tobacco smoke products: the judgement on the direct unconstitutionality action - ADI no. 4.874

The consumption of smoke products, whether or not derived from tobacco, is, in itself, a complex and sensitive issue in social terms, whose the impact affects the individual right to health. Anvisa's regulatory option in technically detecting the contingencies of specific cases in society assures fundamental rights, as in the case of combating diseases associated with smoking.

As it is more generally known, the private economic activity of commercialization and production of tobacco and its derivatives in the country is authorized by the State, permitting the use of this product by adults who wish to smoke. A priori, both the manufacturing industry and the smokers are aware of the health hazards that this habit can cause, especially because of its massive disclosure by the State.

With restrictions on the advertising of tobacco smoke products, initiated in 1980, the National Council of Self-Regulatory Advertising (Conar) introduced ethical rules drafted especially for such products and

52 In the original: "Articolo 7 Regolamentazione degli ingredienti [...] 7. Gli Stati membri vietano l'immissione sul mercato dei prodotti del tabacco contenenti aromi in qualsiasi dei loro elementi quali i filtri, le cartine, le confezioni, le capsule o le caratteristiche tecniche che consentono di modificare l'odore o il gusto dei prodotti del tabacco interessati o la loro intensità di fumo. I filtri, le cartine e le capsule non devono contenere tabacco o nicotina." (GAZZETTA UFFICIALE DELL'UNIONE EUROPEA. *Direttiva 2014/40/UE del Parlamento Europeo e del Consiglio del 3 de aprile 2014* sul ravvicinamento delle disposizioni legislative, regolamentari e amministrative degli Stati membri relative alla lavorazione, alla presentazione e alla vendita dei prodotti del tabacco e dei prodotti correlati e che abroga la direttiva 2001/37/CE. 29 aprile del 2014. Available from: <https://is.gd/wxCncC>. Access on: 11 June 2018).

subsequently imposed a visual warning on the packaging, as laid down by Ordinance No. 490 of August 25, 1988, of the Ministry of Health, with the words: "the MINISTRY OF HEALTH warns: smoking is harmful to health."[53]

This activity, however, increasingly became subject to increasing regulation by Anvisa until the issuance of Resolution RDC No. 14, of 2012, which has restricted the use of additives in tobacco smoke products.[54] In practice, the rule never came into force. It should be pointed out, however, that flavored smoke products, such as mentholated cigarettes, have never ceased to be consumed by Brazilians, because of the extensive smuggling in the country.

Just one day before it became effective, in 2013, an injunction by Justice Rosa Weber suspended the validity of the rule until the case was tried by the Federal Supreme Court. The suspension was motivated by the Direct Unconstitutionality Action – ADI No. 4.874 – judged by the National Confederation of Industry, which questions Anvisa's ordinance to, in a general and abstract character, to, among other things, issue a regulatory act that prevents the use of flavoring and scent additives, such as cinnamon, mint, chocolate, vanilla, and others, that mask the taste of smoke in smoking products.[55]

The National Confederation of Industry used to consider unconstitutional the final part of subsection XV of art. 7 of Law No. 9.782 of 1999[56] and Resolution No. 14 of RDC No. 14 of 2012, for violation of the principles of legal certainty, equality, consumer freedom, proportionality, and violation of the fundamental right to trademark, described in articles 2, 5, II, and 37, caption, of the Federal Constitution.

The legal opinion of the States Attorney Office strived for the possibility of the regulatory agencies being able to elaborate general and abstract norms related to the corresponding sector under their supervision. Therefore, the federal ministerial body defended the thesis that Anvisa could make alterations within the legal framework –, as long as they were based on principles and directives of its particular field, given to them by the ordinary legislative procedure and by the Constitution of the Republic. Thus, Anvisa should not only reproduce the legal requirements, provided that they envisage a new constitutional right or neoconstitutionalism, oriented towards administrative efficiency.

The then President of the Republic, Dilma Rousseff, stated that the regulation of smoke products is within the regulatory competence of Anvisa, which can elaborate norms of a general and non-concrete nature that are in favor of the collective interest to regulate the market players. According to her, the sanitary regulation aimed at hampering the attractiveness of smoking and discouraging future acquisitions through curbing nicotine addiction by children and adolescents, based on technical studies. However, the tobacco industry claimed that, in addition to the product being lawful, such rule infringed consumers' freedom of choice (autonomy of the will).

The AGU has stated that Resolution RDC No. 14 of 2012 is a rule of enforceability, with objectives and actions described in Articles 9 and 10 of the CQCT, signed by more than 180 countries and incorporated into the Brazilian legal framework by Decree No. 5,658, dated January 2, 2006,[57] which holds a hierarchical

53 BRASIL. Ministério da Saúde. Portaria nº 490, de 25 de agosto de 1988. Dispõe sobre as inscrições nos maços de cigarro e outras formas de embalagem de fumo sobre o perigo de fumar à saúde. *Diário Oficial da União,* Brasília, 26 ago. 1988.

54 BRASIL. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada – RDC n° 14, de 15 de março de 2012. Dispõe sobre os limites máximos de alcatrão, nicotina e monóxido de carbono nos cigarros e a restrição do uso de aditivos nos produtos fumígenos derivados do tabaco, e dá outras providências. *Diário Oficial da União*, Brasília, 15 mar. 2012. Available from: <https://is.gd/U1UwEa>. Access on: 21 mar. 2018.

55 BRASIL. Supremo Tribunal Federal. *Ação Direta de Inconstitucionalidade nº 4.87*4. Relator Ministra Rosa Weber. Julgamento em 1º fev. 2018. Available from: <http://portal.stf.jus.br/processos/detalhe.asp?incidente=4328586>. Access on: 10 Feb. 2018.

56 BRASIL. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. *Diário Oficial da União*, Brasília, 26 jan. 1999b. Available from: <http://www.planalto.gov.br/ccivil_03/leis/L9782.htm>. Access on: 20 Feb. 2018.

57 BRASIL. Decreto nº 5.658, de 2 de janeiro de 2006. Promulga a Convenção-Quadro sobre Controle do Uso do Tabaco, adotada pelos países membros da Organização Mundial de Saúde em 21 de maio de 2003 e assinada pelo Brasil em 16 de junho de 2003.

position of ordinary law. In the conception of the AGU, Resolution RDC No. 14, of 2012, has a regulatory character and sets measures for the reduction of the demand for tobacco, besides clarifying that the addition of ingredients to the cigarette would serve as a taste stimulus that generates sensations inducing consumption, a situation that is contrary to the legal precepts.

According to Anvisa, the matter is regulated according to the limits of its institutional mission to monitor and control the risks to public health, without impeding the use of products and services that are subject to sanitary surveillance, defending only the protection of the youngest people against encouragement of tobacco use. The Federal Senate pointed out that there was no reflex offense to the Constitution and that, therefore, the sanitary regulation is constitutional.

The National Confederation of Industry understands that it is for the formal law to impose limitations on the freedom of initiative, especially in the prohibition of substances, given their abstract nature, generality and undefined recipients, based on art. 1º, IV, and on art. 170, sole paragraph, of the Federal Constitution. The Tobacco Industry Interstate Trade Union (Sinditabaco) has required admission on the demand as amici curiae, to the disadvantage of the rule, for understanding that it controls consumer's choices.

In a ruling delivered on February 1, 2018, Anvisa's standard against cigarette additives came into effect. This was because there was a 5-5 tie, for and against Anvisa's rule. Justice Luís Roberto Barroso declared himself unable to attend and did not participate in the discussions. In order to change or overturn Anvisa's rule, at least 6 votes were necessary.

The vote of the rapporteur, Justice Rosa Weber, affirmed that Anvisa's regulatory performance was legitimate in the case of tobacco control, based on the limits set by law and the public policies established by the central administration. Therefore, she voted for the rejection of the request of unconstitutionality of Resolution RDC No. 14, of 2012 based on the citizens' right to health protection and the right to information.

Accompanying the rapporteur were Justices Cármen Lúcia, Edson Fachin, Celso de Mello, and Ricardo Lewandowski. On the other hand, Justices Luiz Fux, Alexandre de Moraes, Dias Toffoli and Gilmar Mendes dissented from the rapporteur's opinion as they considered that there was extrapolation of legislation procedures by Anvisa, provided that all tobacco products are classified as a source of health hazard, and their restriction departs from its area of expertise, whether as a matter of precaution or urgency and partly by Justice Marco Aurélio, who had already positioned himself on the limit of Anvisa to regulatory power in the Direct Unconstitutionality Action, ADI No. 4.874, which is applied in the executive domain, with a supervisory nature, by attributing the exclusivity of the National Congress to prohibit any product within the Brazilian territory, supported by Article 25 of the Transitional Constitutional Provisions Act.[58]

Thus, the Plenary of the Federal Supreme Court, this time, pointed out the exemplary argument:

> The Court, as a whole, heard of the direct action, in accordance to the terms of the Rapporteur. Specifically, with respect to the main request, i.e. that of declaration of unconstitutionality of art. 7, III, and XV, in fine, of Law 9.782/1999, by majority vote and in the terms of the Rapporteur's vote, partly dismissed the application, due to Justice Marco Aurélio. Regarding the successive requests, related to the rules of Resolution 14/2012, by Anvisa´s Board of Directors, the Court dismissed the action, in a hearing without any binding effect or any effect *erga omnes*, for not having reached the quorum

Diário Oficial da União, Brasília, DF, 2 jan. 2006a. Available from: <http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Decreto/D5658.htm>. Access on: 27 jan. 2018.

58 "Art. 25. Within one hundred and eighty days from the proclamation of the Constitution, subject to this extension, by law, all legal provisions that assign or delegate to the executive branch the competency pointed out by the Constitution to the National Congress, especially in respect to: I - normative action;"

In the original: "Art.25.Ficam revogados, a partir de cento e oitenta dias da promulgação da Constituição, sujeito este prazo a prorrogação por lei, todos os dispositivos legais que atribuam ou deleguem a órgão do Poder Executivo competência assinalada pela Constituição ao Congresso Nacional, especialmente no que tange a: I- ação normativa;" (BRASIL. Constituição (1988). *Constituição da República Federativa do Brasil*. Diário Oficial da União, Brasília, 5 out. 1988. Available from: <http://www.planalto.gov.br/ccivil_03/constituicao/constituicaocompilado.htm>. Access on: 16 Feb. 2018.).

required by Article 97 of the Constitution, thus canceling the injunction granted, in accordance with the Rapporteur's vote. Justice Roberto Barroso did not participate. The trial was presided over by Minister Cármen Lúcia. Plenary, 01.01.2018.[59]

However, the outcome of the decisive voting of the Federal Supreme Court has left a loophole for the tobacco industry, enabling it to file individual lawsuits in state courts of justice. This is because the decision is not binding, that is, companies can try to obtain the release of the additives for sale through actions in other judicial bodies.

Six years after Anvisa approved of its prohibitionist resolution, the noise concerning the ingredients giving characteristic flavors to smoke products was not settled, but in fact, continues in Brazilian society.

6. Conclusion

We intended, with this work, to develop the debate about the limits imposed to Anvisa's normative power and regulatory characteristics by the established Powers, through the use of normative, doctrinaire, and case-law basis of the national and international Law. We noted that the Federal Constitution encompasses a general regulatory power of the Administration, expressly delegated to the State Ministers and, by implication, to governmental institutions, arising from the extension of the principle of legality set forth in article 5, item II, which is intended to protect those administered through constitutional guarantees.

The Constitution contains this general normative power of the Administration, which stems from the principle of legality that directs the political/parliamentary activity (delegitimation) to matters that must be approached under administrative norms. Thus, on the one hand, the public power is directed by the principle of legality, and on the other hand, by the principle of tempered formality. In other words, the regulatory act of Anvisa must conform to the law, which delegates legislative assignment to it, and therefore does not have to devise or conceive the legal/sanitary framework.

Of course, the Legislative Branch would not have the practical means to supervise all regulatory contents under discussion, and this fact allows decisions on what is the best way of acting to be shifted to the Executive Branch, all the more the Parliament no longer possesses much popular representation. It is recognized that the Legislature has long demonstrated signs of unpreparedness to regulate matters that require certain expertise, and it is also not able to follow the very changing aspects of the current social patterns.

In parallel, the Executive's regulatory ability was strengthened by the issuing of general rules on social and economic affairs by regulatory agencies. Thus, the enacting of laws, which is usually reserved for the legislator, granted space to the regulatory agencies, which narrowed their scope of action through direct and specific rules, deriving from the institution's specialization, and with more agile regulations due to the reduced number of participants in the decision making process.

Consequently, it is responsibility of the National Congress to establish public policy guidelines, and of the agencies to make technical choices, introduced by law, without demanding new requirements. Anvisa's regulatory activity generates constant tension in the democratic political conditions of the Federal Legisla-

59 In the original: "O Tribunal, por unanimidade, conheceu da ação direta, nos termos do voto da Relatora. No mérito, relativamente ao pedido principal, de declaração de inconstitucionalidade do art. 7º, III, e XV, *in fine*, da Lei 9.782/1999, por maioria e nos termos do voto da Relatora, julgou improcedente o pedido, vencido, em parte, o Ministro Marco Aurélio. Quanto aos pedidos sucessivos, relativos às normas da Resolução da Diretoria Colegiada da ANVISA 14/2012, o Tribunal julgou improcedente a ação, em julgamento destituído de eficácia vinculante e efeitos *erga omnes*, por não se ter atingido o *quorum* exigido pelo artigo 97 da Constituição, cassando-se a liminar concedida, nos termos do voto da Relatora. Declarou suspeição o Ministro Roberto Barroso. Presidiu o julgamento a Ministra Cármen Lúcia. Plenário, 1º.2.2018. (BRASIL. Supremo Tribunal Federal. *Ação Direta de Inconstitucionalidade nº 4.874*. Relator Ministra Rosa Weber. Julgamento em 1º fev. 2018. Available from: <http://portal.stf.jus.br/processos/detalhe.asp?incidente=4328586>. Access on: 10 Feb. 2018).

tive Branch, which is in charge of producing which is to supervise the creation of general rules in defense of health and performing its fundamentally technical analysis as a regulator,.

In the specific area of health, the legislator defined his autonomy, due to the high political load of the subject matter, and therefore, it is not up to Anvisa to decide, even under the argument on the grounds of protecting the public health. At this time, there was no unconstitutionality because of the withdrawal of Resolution – RDC No. 14, of 2012 on scented and flavored smoke products, as requested in the Direct Action of Unconstitutionality – ADI No. 4874. However, it is expected that the case returns to the Supreme Court itself, as an Extraordinary Appeal, depending on a change of understanding with concrete results or a change in the composition of the Court.

In any case, Anvisa's discretionary power has to be democratically controlled and internally assisted by the regulatory impact assessment, given its review, which must inquire about the consistency of the content. With regard to the issue of popular sovereignty, the Executive and Legislative powers should discuss the implicit and explicit reasons concerning the adequacy of acts connected to the targeted ends or activities.

Alternative means of regulating social life, designed to guarantee the citizen´s fundamental rights, serve to attend to or represent social interests as well as interest groups. For this reason, it is the responsibility of the National Congress to demand the performance from regulatory agencies. After all, in the old bureaucratic interventionist model, the Executive would set the sectorial policy, while in the regulatory model, the National Congress establishes this policy through the law.

As you can see, Anvisa has interfered in the economic sphere and in social relations and, at times, has gone much beyond them and still at other times, within the limits of the law, but still exercising its regulating functions on the borderline of the social and constitutional will, whose ideological or even emotional intensity shifts to the regulatory power and its features. In the first aspect, the Judiciary has decided in favor of the fundamental rights, by invalidating the challenged regulation, while in the second, the legislature has acted to achieve the social efficiency demanded.

The controversy concerning limiting the gradual intrusion of the Executive Power in activities theoretically pertaining to legislative regulation shows that the assignment of normative power to the agencies does not hold a solution or deductive answer in this respect. However, the aim of this work is that we recognize the determining reasons for the definition of Anvisa's regulatory limits and, by extension, the limits of the other regulatory agencies.

Finally, this analysis was focused on the discussion of Anvisa's normative (in)competency, while previous reviews examined the impact of the additives that give aroma and flavor to tobacco products, harming the individual's health.[60,61,62,63,64,65,66] Future researches could explore the continuity of the legal standoff - of

60 WORLD HEALTH ORGANIZATION. *Case studies for regulatory approaches to tobacco products:* menthol in tobacco products. Geneva: WHO/NMH/ PND/18.1, 2018. Available from: <https://is.gd/WXPLg8>. Access on: 10 jun. 2018.

61 KOWITT, Sarah D. et al. Perceptions and Experiences with Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies.*International Journal of Environmental Research and Public Health*,v. 14, n. 4, p. 338, 2017.Available from: <https://doi.org/10.3390/ijerph14040338>. Access on: 10 June 2018.

62 PAUMGARTTEN, Francisco José Roma; GOMES-CARNEIRO, Maria Regina; OLIVEIRA, Ana Cecilia Amado Xavier de. The impact of tobacco additives on cigarette smoke toxicity: a critical appraisal of tobacco industry studies. *Cadernos de Saúde Pública*, 33 Sup 3, p. e00132415, 2017. Available from: <https://doi.org/10.1590/0102-311X00132415>. Access on: 10 June 2018.

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thresholds (un)favorable to the associations and pro-tobacco industries union –, as well as the attitudinal and behavioral results of the Brazilian people after the decision of the Federal Supreme Court.

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